



# UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE  
United States Patent and Trademark Office  
Address: COMMISSIONER FOR PATENTS  
P.O. Box 1450  
Alexandria, Virginia 22313-1450  
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/882,530	06/15/2001	Derrick A. Richardson	485772003600	9930
7590	01/15/2004			
Rimas Lukas P.O. Box 3295 Half Moon Bay, CA 94019				
EXAMINER LEWIS, PATRICK T				
ART UNIT		PAPER NUMBER		
1623				

DATE MAILED: 01/15/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	09/882,530	RICHARDSON ET AL.	
	<b>Examiner</b>	<b>Art Unit</b>	
	Patrick T. Lewis	1623	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 20 October 2003.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 1-33 is/are pending in the application.
- 4a) Of the above claim(s) 24 and 25 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-7, 10-20, 23 and 26-33 is/are rejected.
- 7) ☒ Claim(s) 8, 9, 21 and 22 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. §§ 119 and 120

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All   b) ☐ Some \* c) ☐ None of:  
1. ☐ Certified copies of the priority documents have been received.  
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  
\* See the attached detailed Office action for a list of the certified copies not received.
- 13) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.  
a) ☐ The translation of the foreign language provisional application has been received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

#### Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)                      4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)                      5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 08182003 .                      6) ☐ Other: \_\_\_\_\_

## **DETAILED ACTION**

### ***Election/Restrictions***

1. Applicant's election without traverse of Invention I (claims 1-23) in Paper No. 8 dated October 21, 2002 is acknowledged.
2. Claims 24-25 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Election was made **without** traverse in Paper No. 8 dated October 21, 2002.

### ***Applicant's Response dated October 20, 2003***

3. In the Response filed October 20, 2003, claim 1 was amended and claims 26-33 were added. Applicant presented arguments directed to the rejection of claims 1-23 under 35 U.S.C. 103(a). Claims 1-33 are pending. Claims 24-25 are withdrawn from consideration as being drawn to a nonelected invention. An action on the merits of claims 1-23 and 26-33 is contained herein below.
4. Applicant's arguments with respect to claims 1-23 have been considered but are moot in view of the new ground(s) of rejection.

### ***Claim Rejections - 35 USC § 102***

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

6. Claims 1-3, 5-7, 12-13, 15, 19, 23, and 26-33 are rejected under 35 U.S.C. 102(b) as being anticipated by Forsythe, Jr. et al. US 4,214,993 (Forsythe).

Forsythe discloses an apparatus for separating fluids comprising an extraction cartridge, having an enlarged middle portion, tapered inward toward its lower end and adapted to receive said fluids and a tubular lower portion communicating with the upper portion, separating column material disposed in the lower portion, the bottom end of the lower portion defining a nozzle for fluids passing through the lower portion, a primary container, the interior lower end of the container defining interiorly extending radial guides for positioning the lower portion of the extraction cartridge and protecting the nozzle, the top end of each of the extraction cartridge and the primary container defining enlarged sections of equal inside diameter, a closure member insertable into the top end of either the extraction cartridge or the primary container, the extraction cartridge middle portion and the primary container each formed to have a mating taper to permit the nesting of the cartridge in the container, whereby the container and the closure member protects the seal the separating column material and the nozzle against loss of liquid and damage (column 1, lines 40-61). The extraction cartridge **16** and the containers or caps **32** and **36** used in this technique are adapted to be nested together (columns 3-5; Figures 1-3). The extraction cartridge **16** is comprised essentially of three section, a middle portion **18** which is adapted to hold a fluid, a upper portion **20** which has an enlarged internal diameter to accommodate the stem portion **12** of the cap **10**

Art Unit: 1623

and which forms an exterior step shoulder **22** which facilitates positioning the extracting cartridge in a holder, such as the swinging bucket of a centrifuge. The extraction cartridge **16** is seen to comprise at least three body portions and at least two bearing surfaces. The examiner has interpreted a "bearing surface" to mean any surface capable of bearing weight including slanted or tapered surfaces. The diameter of extraction cartridge **16** varies from top to bottom and is thus capable of use with collecting tubes of different inner diameters. Finally there is a lower portion **24** which is a greatly reduced diameter and forms a constant diameter interior tube or column in which there may be disposed a separating material **26**. Spherical porous supports **30** (frits), made of a typical inert plastic, are placed at the top and bottom of the particular separating material **26** formed in the column. The middle portion **18** is tapered inwardly towards the lower end to accommodate its being nested or stacked into the third element making up the nested separating apparatus, namely the first cup **32**. The lower portion **34** of the first container **32** is tapered inwardly towards the lower end so that it too may be nested or stacked with a fourth piece of the nested separating apparatus, cup **36**. The first container **32** also forms an exterior shoulder **38**. A similar shoulder **40** is formed on the second cup **36** between the lower portion **42** of the container **32** and an enlarged upper portion **44**. The bottom of both the first container **32** and the second container **36** are formed with an annular flange or ring **49** which provides a suitable stand support for holding both the waste container and the recovery cup in an upright position when placed upon a horizontal surface. Some extraction cartridges may

Art Unit: 1623

contain a filter in the reservoir for the purpose of trapping solid, particulate or fibrous materials that may be present in the sample.

***Claim Rejections - 35 USC § 103***

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

8. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

9. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

10. Claims 4, 10-11, 14, 16-18, and 20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Forsythe, Jr. et al. US 4,214,993 (Forsythe) in combination with BIO-RAD, Life Science Research Products Catalog (1993), pages 57 and 60-63 (BIO-RAD).

Claims 4, 10-11, 14, 16-18, 20, and 23 are drawn to a filter column comprising: a body having a passageway extending therethrough, said body comprising at least a first body portion, a second body portion, and a third body portion, where an outer diameter of said first body portion is greater than an outer diameter of said second body portion, and where said outer diameter of said second body portion is greater than an outer diameter of said third body portion; a filter located within said passageway, said filter adapted to isolate nucleic acids from said liquid sample; and a plurality of bearing surfaces on an outer surface of said body, at least two of said bearing surfaces being adapted to seat on at least two of the collection tubes, each of the collection tubes having differently-sized openings, said plurality of bearing surfaces including at least a first bearing surface located between said first and second body portions, and a second bearing surface located between said second and third body portions. Claim 4 limits the filter column to columns wherein the filter is located with a portion of the passageway in the second body portion. Claims 10-11 are drawn to columns wherein the lid includes a hinge integral to the body. Claims 14, 16-18, and 20 limit the dimensions of the filter column.

Forsythe teaches an apparatus for separating fluids comprising an extraction cartridge, having an enlarged middle portion, tapered inward toward its lower end and adapted to receive said fluids and a tubular lower portion communicating with the upper

Art Unit: 1623

portion, separating column material disposed in the lower portion, the bottom end of the lower portion defining a nozzle for fluids passing through the lower portion, a primary container, the interior lower end of the container defining interiorly extending radial guides for positioning the lower portion of the extraction cartridge and protecting the nozzle, the top end of each of the extraction cartridge and the primary container defining enlarged sections of equal inside diameter, a closure member insertable into the top end of either the extraction cartridge or the primary container, the extraction cartridge middle portion and the primary container each formed to have a mating taper to permit the nesting of the cartridge in the container, whereby the container and the closure member protects the seal the separating column material and the nozzle against loss of liquid and damage (column 1, lines 40-61). The extraction cartridge **16** and the containers or caps **32** and **36** used in this technique are adapted to be nested together (columns 3-5; Figures 1-3). The extraction cartridge **16** is comprised essentially of three section, a middle portion **18** which is adapted to hold a fluid, a upper portion **20** which has an enlarged internal diameter to accommodate the stem portion **12** of the cap **10** and which forms an exterior step shoulder **22** which facilitates positioning the extracting cartridge in a holder, such as the swinging bucket of a centrifuge. The extraction cartridge **16** is seen to comprise at least three body portions and at least two bearing surfaces. The examiner has interpreted a "bearing surface" to mean any surface capable of bearing weight including slanted or tapered surfaces. The diameter of extraction cartridge **16** varies from top to bottom and is thus capable of use with collecting tubes of different inner diameters. Finally there is a lower portion **24** which is



Art Unit: 1623

a greatly reduced diameter and forms a constant diameter interior tube or column in which there may be disposed a separating material **26**. Spherical porous supports **30** (frits), made of a typical inert plastic, are placed at the top and bottom of the particular separating material **26** formed in the column. The middle portion **18** is tapered inwardly towards the lower end to accommodate its being nested or stacked into the third element making up the nested separating apparatus, namely the first cup **32**. The lower portion **34** of the first container **32** is tapered inwardly towards the lower end so that it too may be nested or stacked with a fourth piece of the nested separating apparatus, cup **36**. The first container **32** also forms an exterior shoulder **38**. A similar shoulder **40** is formed on the second cup **36** between the lower portion **42** of the container **32** and an enlarged upper portion **44**. The bottom of both the first container **32** and the second container **36** are formed with an annular flange or ring **49** which provides a suitable stand support for holding both the waste container and the recovery cup in an upright position when placed upon a horizontal surface. Some extraction cartridges may contain a filter in the reservoir for the purpose of trapping solid, particulate or fibrous materials that may be present in the sample.

The instantly disclosed filter column differs from the column described by Forsythe in that Forsythe: 1) does not teach a filter located within the passageway of the second body portion, 2) does not teach a column wherein the lid includes a hinge, and 3) does not teach the dimensions of the filter column.

BIO-RAD describes a low-pressure chromatography column comprising a body having a passageway extending therethrough (page 62). The body of the column

Art Unit: 1623

comprises three sections wherein the top section has a greater diameter than the middle section which has a greater diameter than the bottom section. The top section contains an end cap and a 10 mL reservoir. The middle section has a 2 mL be volume and contains a porous polymer bed support. An integral adaptor ring allows the column to be used with most 1.5 ml microtubes and 12 x 75 mm test tubes in spin column applications

It would have been obvious to one of ordinary skill in the art at the time of the invention to manufacture the columns of Forsythe within the dimensions of the instantly claimed filter column. BIO-RAD is seen to teach columns within applicant's specified dimensions. It would have been obvious to one of ordinary skill in the art to formulate the column of Forsythe into the dimensions disclosed by BIO-RAD. One would have been motivated to do so in order to utilize conventionally sized collecting tubes with the filter column. The differences between Forsythe and the instantly claimed filter column, as it relates to the location of the filter media within the column and the use of a top comprising a hinge attached to the body of the column, are seen as one of design choice. In the absence of persuasive evidence that the particular configuration of the claimed column is significant, the instantly claimed filter column is indeed prima facie obvious.

### ***Conclusion***

11. Claims 1-33 are pending. Claims 24-25 are withdrawn from consideration as being drawn to a nonelected invention. Claims 1-7, 10-20, 23, and 26-33 are rejected.

Art Unit: 1623

Claims 8-9 and 21-22 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims. No claims are allowed.

12. Applicant's submission of an information disclosure statement under 37 CFR 1.97(c) with the fee set forth in 37 CFR 1.17(p) on August 18, 2003 prompted the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 609(B)(2)(i). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

Art Unit: 1623

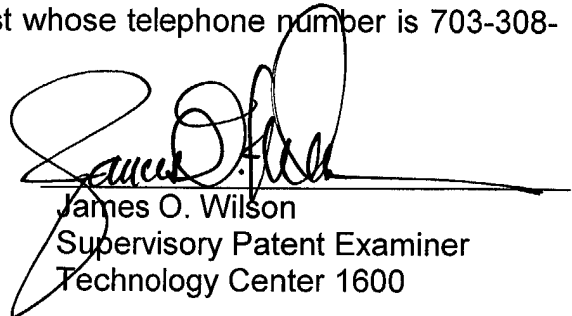
**Contacts**

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Patrick T. Lewis whose telephone number is 703-305-4043. The examiner can normally be reached on M-F 8:00 am to 4:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James O. Wilson can be reached on 703-308-4624. The fax phone numbers for the organization where this application or proceeding is assigned are 703-305-3014 for regular communications and 703-305-3014 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

Patrick T. Lewis, PhD  
Examiner  
Art Unit 1623



James O. Wilson  
Supervisory Patent Examiner  
Technology Center 1600

ptl  
January 10, 2004